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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/668,564	09/23/2003	Nicholas Michael Morton	674543-2004	3906

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EXAMINER	
WILLIAMS, LEONARD M	
ART UNIT	**PAPER NUMBER**
1617	
MAIL DATE	**DELIVERY MODE**
09/20/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/668,564	MORTON ET AL.	
	Examiner	Art Unit	
	Leonard M. Williams	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-51* is/are pending in the application.

4a) Of the above claim(s) *1-13 and 27-51* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *14-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/25/04, 9/23/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Detailed Action

Election/Restrictions

Applicant's election with traverse of Group II (claims 14-26 and 32) in the reply filed on 07/02/2007 is acknowledged. The traversal is on the ground(s) that there is no burden on the examiner for search purposes. This is not found persuasive because the examiner has clearly indicated that the search for the invention of Group II would not be coextensive with the other two inventions detailed in the restriction requirement.

The requirement is still deemed proper and is therefore made FINAL.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 20 recites the limitation "wherein the atheroprotective lipid profile" in claim 14 from which it depends there is no reference to the atheroprotective lipid profile. There is insufficient antecedent basis for this limitation in the claim.

Claims 22 and 23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 22 recites "...reduction of 11b-HSD1 levels". Claim 23 recites "...red-action of 11b-HSD1 levels". Both claims are deemed indefinate as the independent claim from which they depend recite "...reduces 11b-HSD1 activity".

It is not clear that reduced levels as claimed are the same as reduced activity as claimed. Further clam 23 includes the term red-action which the examiner assumes should be reduction.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 14-25 rejected under 35 U.S.C. 102(b) as being anticipated by Gordon et al. (Reduction of Atherosclerosis by Administration of Dehydroepiandrosterone, J. Clin. Invest., 1988, vol. 82, pp. 712-720) as evidenced by Apostolova et al. (Dehydroepiandrosterone inhibits the amplification of glucocorticoid action in adipose tissue, ABSTRACT, Am. J, Physiol. Endocrinol. Metab., 2005, vol. 5 pp. 288).

Gordon et al. teach, on page 712-abstract, that animals given aortic endothelial injury and treated with DHEA had an almost 50% plaque size reduction. Fatty infiltration of the heart and liver were also reduced. Further the results show that high levels of plasma DHEA inhibit the development of atherosclerosis and low DHEA-sulfate plasma levels are associated with an enhanced risk of cardiovascular mortality. Apostolova et al. disclose, in the abstract, that DHEA exerts beneficial effects on blood glucose levels and insulin sensitivity in obese rodents and humans and causes

downregulation of 11beta-HSD1 and a dose-dependent reduction of its oxoreductase activity. Further, the effects of DHEA were comparable with the PPARgamma agonist rosglitazone anticipating the "...method for reducing cardiovascular disease risk in an animal at risk of cardiovascular disease, comprising administeing...an agent which reduces 11b-HSD1 activity..." of claim 14, the "...method...wherein 11b-HSD1 levels are lowered by an agent which modulates the expression of the endogenous 11b-HSD1 gene.." of claim 15, , the "...method...wherein 11b-HSD1 levels are lowered by an agent which modulates 11b-HSD1 mRNA transcription of translation..." of claim 16, the "...method...wherein 11b-HSD1 levels are lowered by an agent which inhibits 11b-HSD1 synthesis or activity..." of claim 17, and the "...method...wherein the agent increases insulin sensitivity..." of claim 24.

Claims 18-22 and 23 are anticipated as the compounds disclosed in Gordon et al. inhibit 11βHSD1 and as such inherently reduce the apoCIII levels, increase PPARα and/or PPARγ levels, increase the HDL cholesterol levels, reduce the plasma triglyceride levels, etc....

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Gordon et al. as applied to claims 14-25 above, and further in view of Hermanowski-Vosatka et al. (PPARα Agonists Reduce 11β-Hydroxysteroid Dehydrogenase Type 1 in the Liver, 2000, Biochemical and Biophysical Research Communications, Vol. 279, pp. 330-336).

Gordon et al. is as set forth above.

Gordon et al. does not disclose the use of a PPARα agonist in conjunction with an agent that reduces 11β-HSD1 activity in a method for the promotion of an atheroprotective lipid profile.

Hermanowski-Vosatka et al. teach, on pages 332-333, that administration of fenofibrate (a PPARα agonist) in mice decreased 11βHSD1 expression by two-to threefold as determined by real time PCR.

It would have been obvious to one of ordinary skill in the art at the time of the invention was made to use fenofibrate (a PPARα agonist) as disclosed by Hermanowski-Vosatka et al. in conjunction with an inhibitor of 11βHSD1 as disclosed by Gordon et al. in a method for the promotion of an atheroprotective lipid profile, as Hermanowski-Vosatka et al. teach that fenofibrate reduces the expression of 11βHSD1 and Gordon et al. teaches that DHEA is an inhibitor 11βHSD1 and further Gordon et al. and Hermanowski-Vosatka et al. teach that inhibition of 11βHSD1 is an effective method in the treatment of diabetes, improved glucose tolerance, and insulin sensitivity all pathways involved in the regulation of lipid profiles.

The examiner respectfully points out the following from MPEP 2144.06:
"It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them flows logically from their having been individually taught in the prior art." *In re* Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leonard M. Williams whose telephone number is 571-272-0685. The examiner can normally be reached on MF 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

S. Wang
SHENGJUN WA
PRIMARY EXA

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